

Title 22, California Code of Regulations

ARTICLE 3. Science Advisory Board: Carcinogen Identification Committee and Developmental and Reproductive Toxicant (DART) Identification Committee

§ 12301. Definitions.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.8 and 25249.12, Health and Safety Code.

§ 12302. Science Advisory Board.

(a) There are created in the lead agency two Committees of the Science Advisory Board, the Carcinogen Identification Committee and the DART Identification Committee defined in paragraphs (1) and (2), respectively, of subsection (b) of Section 12102, to advise and assist the Governor and the Director in the implementation of Section 25249.8 of the Act.

(b)(1) The Carcinogen Identification Committee shall be composed of no less than seven (7) members and no greater than eleven (11) members, and shall include experts from among the following areas of specialization: epidemiology, oncology, pathology, medicine, public health, biostatistics, biology, toxicology, and related fields.

(2) The DART Identification Committee shall be composed of no less than seven (7) members and no greater than eleven (11) members, and shall include experts from among the following areas of specialization: epidemiology, developmental toxicology, reproductive toxicology, teratology, medicine, public health, biostatistics, biology, toxicology, and related fields.

(3) The members of the Committees shall be appointed by the Governor and shall serve at the pleasure of the Governor.

The terms shall be for a period of four years, except that any person chosen to fill a vacancy shall be appointed only for the unexpired term of the member whom he or she succeeds. Members of each Committee shall be eligible for reappointment.

(c) The Carcinogen Identification Committee and the DART Identification Committee shall meet not less than once in any calendar year. The Governor shall designate from among the members of each Committee respective Chairpersons who will call and preside over Committee meetings, and shall designate an Executive Secretary who shall be a state employee who has expertise in one or more of the areas of specialization listed in subsection (b). Each Chairperson, with the consent of the other Committee members, shall designate from among the respective Committee members such subcommittees as may be appropriate in fully discharging the responsibilities of that Committee.

(d)(1) Except as otherwise expressly authorized by statute, all meetings of the Committees, and all subcommittee meetings shall be open to the public and convened only after reasonable public notice of the meeting, including the date, time, location and agenda of items of business to be transacted or discussed, has been provided.

(2) All correspondence to or from the Committees, or any subcommittee shall be available for public inspection as provided in the Public Records Act (Government Code Section 6250 et seq.).

(e) Members of the Committees may be asked to provide advice and counsel at formally convened Committee meetings and other subcommittee meetings and individually in response to written materials submitted to them by the lead agency, the Executive Secretary, or the Governor. Each of the two Committees shall act, as a body in making recommendations to the Governor or the lead agency.

(f) A quorum of the Committee shall be a majority of the members appointed to the Committee. An affirmative vote of the majority of the appointed members shall be required for any action of each Committee. A vacancy on a Committee shall not impair the right of the remaining members to exercise all powers of the Committee.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.8, Health and Safety Code.

§ 12303. Compensation.

Members of the Committees shall be entitled to reimbursement for actual and necessary expenses incurred while attending meetings or otherwise carrying out the duties of their respective committees. In addition, members of the Committees shall be entitled to compensation for time spent attending Committee meetings and on the other actual and necessary work of the Committee as determined by the lead agency.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.8, Health and Safety Code.

§ 12304. Financial Disclosure.

Upon appointment and annually thereafter, Committee members shall, consistent with the Political Reform Act of 1974 commencing with Section 81000 through 91015 of the Government Code and Title 2, California Code of Regulations, Division 6, Chapters 1 through 10, make a public disclosure on forms provided of investments in, income from or business positions in any partnership, corporation, or other entity that imports, manufactures, distributes, sells, buys, or uses chemicals that are or may be considered carcinogens or reproductive toxicants. Such disclosure made upon appointment shall cover the twelve-month period immediately prior to the date of appointment. Committee members shall, in addition to the requirements of Sections 81000 through 91015 of the Government Code and Title 2 CCR, Division 6, Chapters 1 through 10, also provide a

description of funding sources for all professional activities undertaken during the twelve months immediately prior to their appointment, and annually thereafter during their service on the Committee. In order to vote on an official action of a Committee, Committee members must be in compliance with Sections 81000 through 91015 of the Government Code and Title 2 CCR, Division 6, Chapters 1 through 10.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.8, Health and Safety Code.

§ 12305. Powers and Duties.

(a) As an advisory body to the Governor and the lead agency, the Carcinogen Identification Committee may undertake the following activities:

(1) Render an opinion, pursuant to subdivision (b) of Section 25249.8 of the Act, as to whether specific chemicals have been clearly shown, through scientifically valid testing according to generally accepted principles, to cause cancer.

(2) Identify bodies which are considered to be authoritative and which have formally identified chemicals as causing cancer.

(3) Identify specific chemicals that are required by state or federal law to have been tested for potential to cause cancer but which have not been adequately tested.

(4) Review or propose standards and procedures for determining carcinogenicity of chemicals.

(5) Review or propose standards, procedures and definitions related to the implementation, administration or interpretation of the Act in support of the duties specified in the Section 25249.8 of the Act and upon request by the lead agency.

(b) As an advisory body to the Governor and the lead agency, the DART Identification Committee may undertake the following activities:

(1) Render an opinion, pursuant to subdivision (b) of Section 25249.8 of the Act, as to whether specific chemicals have been clearly shown, through scientifically valid testing according to generally accepted principles, to cause reproductive toxicity.

(2) Identify bodies which are considered to be authoritative and which have formally identified chemicals as causing reproductive toxicity.

(3) Identify specific chemicals that are required by state or federal law to have been tested for potential to cause reproductive toxicity but which have not been adequately tested.

(4) Review or propose standards and procedures for determining reproductive toxicity of chemicals.

(5) Review or propose standards, procedures and definitions related to the implementation, administration or interpretation of the Act in support of the duties specified in Section 25249.8 of the Act and upon request by the lead agency.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.8, Health and Safety Code.

§ 12306. Chemicals Formally Identified by Authoritative Bodies.

(a) Pursuant to Section 25249.8(b) of the Act, a chemical is known to the state to cause cancer or reproductive toxicity if the lead agency determines that an authoritative body has formally identified the chemical as causing cancer or reproductive toxicity, as specified in this section.

(b) A “body considered to be authoritative” is an agency or formally organized program or group which utilizes one of the methods set forth in subsection (d), for the identification of chemicals, and which the Carcinogen Identification Committee has identified as having expertise in the identification of chemicals as causing cancer or the DART Identification Committee has identified as having expertise in the identification of chemicals as causing reproductive toxicity. For purposes of this section, “authoritative body” means either a “body considered to be authoritative” in the identification of chemicals as causing cancer by the Carcinogen Identification Committee or a “body considered to be authoritative” in the identification of chemicals as causing reproductive toxicity by the DART Identification Committee. The Carcinogen Identification Committee and the DART Identification Committee shall have the authority to revoke or rescind any determination that a body is authoritative on the grounds that the respective Committee no longer considers the body to have expertise in the identification of chemicals as causing cancer or reproductive toxicity, respectively, in which case chemicals listed pursuant to this section prior to the effective date of the revocation shall remain on the list. Nothing in this section shall be construed to limit or otherwise interfere with such authority.

(c) The lead agency shall determine which chemicals have been formally identified by an authoritative body as causing cancer or reproductive toxicity.

(d) For purposes of this section a chemical is “formally identified” by an authoritative body when the lead agency determines that:

(1) the chemical has been included on a list of chemicals causing cancer or reproductive toxicity issued by the authoritative body; or is the subject of a report which is published by the authoritative body and which concludes that the chemical causes cancer or reproductive toxicity; or has otherwise been identified as causing cancer or

reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action; and

(2) the list, report, or document specifically and accurately identifies the chemical, and has been:

(A) Reviewed by an advisory committee in a public meeting, if a public meeting is required, or

(B) Made subject to public review and comment prior to its issuance, or

(C) Published by the authoritative body in a publication, such as, but not limited to, the federal register for an authoritative body which is a federal agency, or

(D) Signed, where required, by the chief administrative officer of the authoritative body or a designee, or

(E) Adopted as a final rule by the authoritative body, or

(F) Otherwise set forth in an official document utilized by the authoritative body for regulatory purposes.

(e) For purposes of this section, “as causing cancer” means that either of the following criteria has been satisfied:

(1) Sufficient evidence of carcinogenicity exists from studies in humans. For purposes of this paragraph, “sufficient evidence” means studies in humans indicate that there is a causal relationship between the chemical and cancer.

(2) Sufficient evidence of carcinogenicity exists from studies in experimental animals. For purposes of this paragraph, “sufficient evidence” means studies in experimental animals indicate that there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains, in multiple experiments (e.g., with different routes of administration or using different dose levels), or, to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset.

(f) The lead agency shall find that a chemical does not satisfy the definition of “as causing cancer” if scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria of subsection (e), paragraph (1) or subsection (e), paragraph (2).

(g) For purposes of this section, “as causing reproductive toxicity” means that either of the following criteria have been satisfied:

(1) Studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity, or

(2) Studies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.

(h) The lead agency shall find that a chemical does not satisfy the definition of “as causing reproductive toxicity” if scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria of subsection (g), paragraph (1) or subsection (g), paragraph (2).

(i) At least 60 days prior to adding a chemical determined to have been formally identified by an authoritative body as causing cancer or reproductive toxicity to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency shall cause to be published in the California Regulatory Notice Register a notice identifying the authoritative body and the chemical, and stating the lead agency’s intention to cause the chemical to be added to the list. Copies of the notice shall be provided to the Carcinogen Identification Committee or the DART Identification Committee, as appropriate, to permit the appropriate Committee at least 30 days to review and comment on the proposed action. Within 30 days following the publication of the notice, interested parties, including any member of the appropriate Committee, shall submit to the lead agency their written objections to the addition of the chemical to the list of chemicals known to the state to cause cancer or reproductive toxicity, along with any supporting documentation. Objections shall be made on the basis that there is no substantial evidence that the criteria identified in subsection (e) or in subsection (g) have been satisfied. The lead agency shall review such objections. If the lead agency finds that there is no substantial evidence that the criteria identified in subsection (e) or in subsection (g) have been satisfied, the lead agency shall refer the chemical to the appropriate Committee to determine whether, in the Committee’s opinion, the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity.

(j) Subsequent to the addition of a chemical determined to have been formally identified by an authoritative body as causing cancer or reproductive toxicity to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency shall reconsider its determination that the chemical has been formally identified as causing cancer or reproductive toxicity if the lead agency finds:

(1) there is no substantial evidence that the criteria identified in subsection (e) or subsection (g) have been satisfied, or

(2) the chemical is no longer identified as causing cancer or reproductive toxicity by the authoritative body.

Reconsideration may be initiated by the lead agency on its own motion, or on a request from an interested party, including any member of the appropriate Committee. The lead agency shall refer chemicals under reconsideration pursuant to this subsection to the appropriate Committee for a recommendation concerning whether the chemical should continue to be included on the list of chemicals known to the state to cause cancer or reproductive toxicity. Pending such reconsideration, the chemical shall remain on the list.

(k) The Carcinogen Identification Committee or the DART Identification Committee may condition any determination that a body is considered to be authoritative upon the subsequent application of the controls set forth in this section to the determination of which chemicals have been formally identified by the body as causing cancer or reproductive toxicity. In the event that this section or any portion thereof is found to be invalid by any court of competent jurisdiction, the Carcinogen Identification Committee or the DART Identification Committee may determine that such invalidation constitutes a failure of the condition. Upon finding such failure of condition, the determination that the body is authoritative shall be deemed to be revoked. Chemicals which the lead agency has determined have been formally identified by the body as causing cancer or reproductive toxicity pursuant to the controls set forth in this section and which have been placed upon the list of chemicals known to the state to cause cancer or reproductive toxicity prior to such revocation shall remain on the list.

(l) The following have been identified as authoritative bodies for purposes of this section for the identification of chemicals as causing reproductive toxicity.

(1) International Agency for Research on Cancer solely as to transplacental carcinogenicity

(2) National Institute for Occupational Safety and Health

(3) National Toxicology Program solely as to final reports of the National Toxicology Program's Center for Evaluation of Risks to Human Reproduction

(4) U.S. Environmental Protection Agency

(5) U.S. Food and Drug Administration

(m) The following have been identified as authoritative bodies for the identification of chemicals as causing cancer.

(1) International Agency for Research on Cancer

(2) National Institute for Occupational Safety and Health

(3) National Toxicology Program

(4) U.S. Environmental Protection Agency

(5) U.S. Food and Drug Administration

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.8 and 25249.12, Health and Safety Code.